UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. HANMI USA, INC., et al. Defendants.	Civil Action No. 11-760 (JAP) **OPINION** *FILE UNDER TEMPORARY SEAL* [REDACTED]

PISANO, District Judge.

Presently before the Court in this patent infringement action is a motion by plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "Astra" or "Plaintiff") for an injunction pending Astra's appeal of this Court's December 12, 2012 claim construction ruling to the United States Circuit Court of Appeals for the Federal Circuit. Astra seeks to enjoin defendants Hanmi, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi" or "Defendants") from marketing and selling their esomeprazole strontium product pending a ruling on the appeal by the Circuit Court. Defendants have opposed the motion. The Court decides the motion without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons below, the motion is denied.

I. BACKGROUND

Plaintiff brought this action alleging that Hanmi infringed U.S Patent No. 5,714,504 (the " '504 patent") and U.S. Patent No. 5,877,192 (the " '192 patent") based upon Hanmi's filing with the U.S. Food and Drug Administration ("FDA") a New Drug Application ("NDA") seeking approval to market an esomeprazole strontium product before the expiration of the patents. On December 12, 2012, the Court issued a claim construction ruling in the case, construing a number of claim terms from the '504 patent and the '192 patent that were in dispute between the parties. *See* D.I. 257, 258. Among the claim terms disputed was the term "alkaline salt," found in certain claims of the '504 patent. Rejecting Astra's arguments for a broad construction of "alkaline salt", the Court adopted Hanmi's proposed construction and construed this term to mean "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt." *Id.*

Shortly before the scheduled bench trial of this matter in May 2013, the parties advised the Court that they had entered a settlement agreement ("Settlement Agreement") and resolved all issues that would have been decided at trial. Specifically, the parties agreed that the patents-in-suit were valid and were not infringed under Court's construction of the relevant claim terms, including the term "alkaline salt." Consequently, on June 3, 2013, the Court entered a Consent Order and Final Judgment and this matter concluded. D.I. 338. However, Astra reserved the right to, and did, appeal the Court's ruling regarding claim construction.

On August 6, 2013, Hanmi received final approval from the FDA to commercially launch its esomeprazole strontium product, and counsel has advised that a launch may be imminent. Astra Br. at 1. Presently before the Court is a motion by Astra seeking an

injunction to prevent Hanmi from marketing and selling its esomeprazole strontium product pending appeal.

II. ANALYSIS

1. Legal Standard

Rule 8(a) of the Federal Rules of Appellate Procedure provides that "[a] party must ordinarily move first in the district court for the following relief: ... (C) an order suspending, modifying, restoring, or granting an injunction while an appeal is pending." Fed. R. App. P. 8(a)(1). In determining whether to grant an injunction pending appeal the Court consider four well-established factors: (1) whether the applicant has made a strong showing that it is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent an injunction; (3) whether issuance of an injunction will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Hilton v. Braunskill*, 481 U.S. 770, 776, 107 S.Ct. 2113, 95 L.Ed.2d 724 (1987); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, Civ. No. 07-2762, 2009 WL 1968900, *1 (D.N.J. Jul. 01, 2009). The movant bears the burden of establishing the relief is warranted and that burden is a "heavy one." 11 Fed. Prac. & Proc. Civ. 2d § 2904 (cited in *Sanofi-Aventis*, 2009 WL 1968900 at *2).

2. Analysis

Turning to the first factor of the analysis, the Court finds that Plaintiff has failed to establish the likelihood of success on the merits of its appeal. Astra's motion centers on its contention that this Court erroneously construed the term "alkaline salt" in the '504 patent[1] by

[1] The term "alkaline salt" appears in independent claims 1, 6 and 7 and by dependence in claims 2 and 4. Claim 1 is representative: "A pharmaceutical formulation for oral administration comprising a pure solid state alkaline salt of the (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl]sulfinyl]- 1H-benzimidazole and a pharmaceutically acceptable carrier." '504 patent, claim 1.

limiting the term to the six named salt species in the specification. During *Markman* proceedings, Astra had argued that the claim term be given a broad construction, specifically, "a basic salt (here, a salt in which (-)-omeprazole is negatively charged) that is suitable for use in a pharmaceutical formulation." In the instant motion, Astra claims that under its proposed construction Hanmi's esomeprazole strontium product would literally infringe at least claim 1 of the '504 patent.

In originally construing the term "alkaline salt", the Court was not persuaded by Astra's arguments and rejected its proposed construction. Rather, the Court determined that the patentee had given a definition to the term "alkaline salt" which governed construction of the claim, and construed the disputed term to mean "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt." The Court relied on, for example, the Abstract of the '504 patent specification, which describes the subject matter of the patent as follows:

> "The novel optically pure compounds Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of [the enantiomers of omeprazole] … processes for the preparation thereof and pharmaceutical preparations containing the compounds as active ingredients, as well as the use of the compounds in pharmaceutical preparations and intermediates obtained by preparing the compounds."

'504 patent, Abstract.

The Court also pointed to the "Detailed Description of the Invention," which similarly states that "[t]he present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salts of the single enantiomers of omeprazole, where R is an alkyl with 1-4 carbon atoms, i.e. Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salts of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole and (-)-5-methoxy-2-[[(4-methoxy-3,5-

dimethyl-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole, where R is an alkyl with 1-4 carbon atoms." '504 patent, col. 2, lines 42-49.

In addressing the present motion, Court has carefully reviewed the parties' current arguments, and has additionally reviewed the parties' papers from the *Markman* proceedings, and the papers submitted in connection with Astra's motion for reconsideration of the Court's claim construction. In support of the present motion for an injunction, Astra raises the same arguments it raised first during the *Markman* proceeding and then for a second time on its motion for reconsideration. Plaintiff has presented nothing new in support of its position--no new evidence or arguments. Having addressed and rejected Astra's arguments at least two times previously, the Court finds no need to restate them here. The Court has thoroughly considered the parties' contentions and finds that there is no basis for its previous claim construction to be disturbed. Consequently, the Court finds that Astra has not established that it is likely to succeed on the merits of its appeal.

The next two factors of the relevant analysis require the Court to look at the respective harms that would be suffered by the parties in the event of the absence or issuance of an injunction. Astra claims that it will be irreparably harmed if Hanmi is permitted to launch their product because it will erode Nexium's (Astra's branded product) market share and pricing power, cause confusion in the marketplace, and cause damage to Astra's reputation. Hanmi responds with a claim that the Settlement Agreement entered into by the parties vitiates any claim by Astra with respect to irreparable harm. Specifically, Hanmi points to sections 5.1 and 5.2 of the Settlement Agreement which state that in the event that a court finds that Hanmi's product infringes Astra's patents, [redacted]

[redacted] if the Federal Circuit or the District Court rules that the Hanmi Product literally infringes the AstraZeneca Patents." Rathinam Decl. Ex. B § § 5.1, 5.2. Hanmi contends that Astra has therefore agreed that any potential damages are calculable and compensable by payment of [redacted]. Hanmi also argues that Astra, having conceded Hanmi cannot be liable for damages caused by [redacted] warrants the imposition of an injunction against Hanmi.

Putting aside the Settlement Agreement, Hanmi contends that there would be no irreparable harm based upon considerations stemming from the fact that Hanmi's product is not a generic of Nexium, but rather is a non AB-rated[2] 505(b)(2)[3] product. As such, in the

[2] Generic drugs generally will be coded "AB" if they meet the FDA's bioequivalence requirements. *See* http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm A generic drug with an AB rating from the FDA is considered therapeutically equivalent to the branded product and, generally speaking, may be substituted by a physician and pharmacist for the brand drug. *See id.* A non-AB rated drug is not automatically substitutable.

[3] The § 505(b)(2) pathway is explained in *Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 227 (3d Cir. 2013) as follows:

> Under § 505(b)(2) of the FDCA, a drug manufacturer may file an NDA for a drug that is not entirely new but is not simply a generic version of a branded drug. For drugs that have changes from a branded drug, such that an ANDA application is unavailable, but whose changes are so slight that a manufacturer may rightly rely on the "full reports of investigations," 21 U.S.C. § 355(b)(1), of the original drug to establish the new drug's safety and efficacy, an NDA may be filed pursuant to § 505(b)(2), even though those investigations "were not conducted by or for the applicant and ... the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted," *id.* § 355(b)(2). The § 505(b)(2) applicant must submit additional data to the FDA that demonstrates that any differences between the original drug and the § 505(b)(2) drug will not affect the § 505(b)(2) drug's safety and efficacy. *See* 21 C.F.R. § 314.54(a) (providing that § 505(b)(2) applications must provide data that supports any modification of the drug from the relied upon NDA). But, having done that, a §

marketplace, Hanmi's product would not be automatically be substitutable by a pharmacist for Nexium. *See* Nelson Decl. ¶ 11. Instead, a physician will be required to write a prescription for "esomeprazole strontium" *Id.* This stands in contrast to future AB-rated generic Nexium products that, according to Hanmi, are anticipated for 2014, for which automatic substitution would be permitted. *Id.* Hanmi argues that the existence of these factors will work to greatly limit the sales growth of the esomeprazole strontium product upon it introduction, and correspondingly, limit any negative effect of that product's launch on Astra's Nexium product. The Court notes, however, that Hanmi has advised that their argument in this regard is incomplete and not based upon a full record. Hanmi states that in order to fully present its argument it requires certain discovery from Astra pertaining to the Nexium market and its future. *See* Letter at D.I. 355.

The Court finds that the parties' Settlement Agreement, contrary to Hanmi's argument, is not necessarily dispositive of the irreparable harm issue, *see Sanofi-Synthelabo v. Apotex*, Inc., 470 F.3d 1368 (Fed. Cir. 2006), but nevertheless finds that the Agreement is relevant to the analysis. The Settlement Agreement provides that Astra may seek damages in the form of [redacted] should it be found that Hanmi's product literally infringes the patents-in-suit. Thus, Astra has an avenue to be substantially compensated in the event of a determination that the sale and marketing of Hanmi's product infringed Astra's patents. This lessens the potential harm to Astra were it to turn out that Hanmi launches an infringing product.

505(b)(2) applicant can avoid preclinical and certain human studies necessary in full NDA applications.

However, as it stands presently, Hanmi for all intents and purposes has prevailed in this litigation, as Astra has conceded non-infringement. Hanmi has received all necessary regulatory approvals and, absent the injunction sought, may launch it esomeprazole strontium product. As Hanmi points out, future market conditions may be such that delaying its launch could mean that its entry into the market is unsuccessful or less successful than it otherwise could be. Nelson Decl. ¶ 29. Hanmi may lose the advantage of being an early entrant into the market, and as noted in detail in the Nelson Declaration, its window of opportunity to enter the market is limited. Id. ¶ 30. These losses to Hanmi may not be entirely compensable, but it is possible that they may be ameliorated by the posting of a bond. Overall, the two harm factors together do not tip the scales of the analysis strongly in either direction, but given the terms of the Settlement Agreement, the Court finds they slightly favor denying an injunction.

The last factor the Court is to examine is the public interest. As Hanmi has prevailed in this litigation, the Court finds that the public interest weighs in favor of denying the injunction. This action arises under the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355 and 35 U.S .C. §§ 156, 271, which is commonly referred to as the "Hatch–Waxman" Amendments. "A central purpose of the Hatch–Waxman Act is 'to enable competitors to bring cheaper, generic ... drugs to market as quickly as possible.'" *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (citing 149 Cong. Rec. S15885 (Nov. 25, 2003)); *see also In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir.1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices—fast."). The various provision of the Amendments are

designed to encourage companies to challenge weak patents in order to bring less expensive generic products to market earlier.

Given the purpose and, indeed, the statutory mandate of Hatch-Waxman, and this litigation having been concluded by an agreement that Hanmi's product does not infringe Astra patents, the Court finds that entry of an injunction to prevent the marketing of Hanmi's esomeprazole product would be contrary to the public interest.

III. CONCLUSION

Having carefully considered and balanced all of the above enumerated factors, the Court concludes that these factors weigh against granting Astra's motion for injunctive relief. Plaintiff's motion, therefore, is denied. An appropriate Order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: September 13, 2013